

- 1 1. (currently amended) An oral matrix pharmaceutical composition comprising
2 doxazosin or a pharmaceutically acceptable salt, solvate, hydrate, enantiomer or
3 mixture thereof, a low viscosity release retarding agent, ~~and~~ a high viscosity release
4 retarding agent, and one or more solubility enhancers.
- 1 2. (original) The composition of claim 1, wherein the release retarding agents include
2 one or more of cellulose derivatives, acrylic acid or methacrylate
3 polymers/copolymers, gums, vinyl alcohol or vinylpyrrolidone based polymers,
4 block copolymers, or polyethylene oxide.
- 1 3. (original) The composition of claim 2, wherein the cellulose derivatives comprise
2 one or more of hydroxypropyl methylcellulose, hydroxypropyl cellulose,
3 hydroxypropyl ethylcellulose, hydroxyethylcellulose, carboxymethylcellulose, or
4 methylcellulose.
- 1 4. (original) The composition of claim 1, wherein the low viscosity release retarding
2 agent comprises between about 5% to about 40% w/w of the composition.
- 1 5. (original) The composition of claim 1, wherein the low viscosity release retarding
2 agent comprises between about 8% to about 25% w/w of the composition.
- 1 6. (original) The composition of claim 1, wherein the high viscosity release retarding
2 agent comprises between about 5% to about 40% w/w of the composition.
- 1 7. (original) The composition of claim 1, wherein the high viscosity release retarding
2 agent comprises between about 8% to about 20% w/w of the composition.
- 1 8. (cancelled)
- 1 9. (original) The composition of claim 1, wherein the one or more solubility enhancers
2 comprises one or more of polyethylene glycols, surfactants, propylene glycol,
3 glycerol, mono-alcohols, higher alcohols, DMSO, dimethylformamide, N, N-
4 dimethylacetamide, 2-pyrrolidone; N-(2-hydroxyethyl) pyrrolidone, N-
5 methylpyrrolidone, 1-dodecylazacycloheptan-2-one and other n-substituted-alkyl-
6 azacycloalkyl- -2-ones.

- 1 10. (original) The composition of claim 1, further comprising one or more
2 pharmaceutically acceptable excipients.
- 1 11. (original) The composition of claim 10, wherein the one or more pharmaceutically
2 acceptable excipients comprise one or more of binders, diluents and
3 lubricant/glidants.
- 1 12. (original) The composition of claim 1, wherein the composition is the form of tablets,
2 capsules, pellets, granules or any other dosage forms suitable for oral administration.
- 1 13. (original) The composition of claim 1, wherein the composition releases the
2 doxazosin over a period of about 12 hours to about 24 hours.
- 1 14. (currently amended) ~~An~~ The oral matrix pharmaceutical composition according to
2 claim 1, further comprising doxazosin or its salt, solvate hydrate, enantiomers or
3 ~~mixture thereof~~, about 5% to about 40% w/w of hydroxypropylmethyl cellulose of
4 high viscosity as the high viscosity release retarding agent, about 5% to about 40%
5 w/w of hydroxypropyl methylcellulose of low viscosity as the low viscosity release
6 retarding agent, about 2% to about 20% w/w of polyethylene glycol, about 15% to
7 about 50% w/w of lactose, about 10% to about 50% w/w of microcrystalline
8 cellulose, about 0.1% to about 3% w/w of magnesium stearate, about 0.1% to about
9 2% w/w of talc and about 0.1% to about 3% w/w of colloidal silicon dioxide.
- 1 15. (currently amended) ~~An~~ The oral matrix pharmaceutical composition according to
2 claim 14, further comprising doxazosin or a salt, solvate, hydrate, enantiomer or
3 ~~mixture thereof~~, about 8% to about 20% w/w of hydroxypropylmethyl cellulose of
4 high viscosity, about 8% to about 25% w/w of hydroxypropyl methylcellulose of low
5 viscosity, about 5% to about 10% w/w of polyethylene glycol, about 20% to about
6 40% w/w of lactose, about 20% to about 40% w/w of microcrystalline cellulose,
7 about 0.1% to about 3% w/w of magnesium stearate, about 0.1% to about 2% w/w of
8 talc and about 0.1% to about 3% w/w of colloidal silicon dioxide.
- 1 16. (currently amended) ~~An~~ The oral matrix pharmaceutical composition according to
2 claim 1, further comprising doxazosin or a salt, solvate, hydrate, enantiomer or
3 ~~mixture thereof~~, about 5% to about 40% w/w of hydroxypropyl methylcellulose of

high viscosity as the high viscosity release retarding agent, about 5% to about 40% w/w of hydroxypropyl methylcellulose of low viscosity as the low viscosity release retarding agent, about 1% to about 20% w/w of sodium alginate and alginic acid, about 5% to about 20% of Eudragit EPO, about 0.1% to about 3% w/w of magnesium stearate, about 0.1% to about 2% w/w of talc and about 0.1% to about 3% w/w of colloidal silicon dioxide.

17. (currently amended) ~~An~~ The oral matrix pharmaceutical composition according to claim 16, further comprising doxazosin or a salt, solvate, hydrate, enantiomer or mixture thereof, about 8% to about 20% w/w of hydroxypropyl methylcellulose of high viscosity as the high viscosity release retarding agent, about 10% to about 25% w/w of hydroxypropyl methylcellulose of low viscosity as the low viscosity release retarding agent, about 2% to about 10% w/w of sodium alginate and alginic acid, about 6% to about 10% w/w of Eudragit EPO, about 0.1% to about 3% w/w of magnesium stearate, about 0.1% to about 2% w/w of talc and about 0.1% to about 3% w/w of colloidal silicon dioxide.

18. (currently amended) A method of treating one or more of hypertension, urinary outflow obstruction and symptoms associated with benign prostatic hyperplasia in a patient in need thereof, the method comprising administering an oral matrix pharmaceutical composition comprising doxazosin or a pharmaceutically acceptable salt thereof, a low viscosity release retarding agent, ~~and~~ a high viscosity release retarding agent, and one or more solubility enhancers.